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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,362	04/18/2005	Dominique Michel	LP-2002	9841
217 7590 04/16/2008 FISHER, CHRISTEN & SABOL 1725 K STREET, N.W. SUITE 1108 WASHINGTON, DC 20006				
EXAMINER YOUNG, SHAWQUITA				
ART UNIT		PAPER NUMBER		
1626				
MAIL DATE		DELIVERY MODE		
04/16/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/520,362

Applicant(s)

MICHEL, DOMINIQUE

Examiner

SHAWQUA YOUNG

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 21-25 and 31-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 21-25 and 31-33, 35 and 36 is/are rejected.
- 7) ☒ Claim(s) 34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-8, 21-25 and 31-36 are currently pending in the instant application. Applicants have amended claims 1-3, 5, 6, 21, 23, 24, 33 and 34 and added new claims 35 and 36 in an amendment filed on December 26, 2007. Upon reexamining the pending claims, the Examiner has found prior art that reads on the instant invention and will reopen prosecution.

I. *Response to Arguments*

Applicant's amendment, filed on December 26, 2007, has overcome the objection of claims 1-8, 21-25 and 31-34 as containing non-elected subject matter and this objection has been withdrawn.

II. *Rejection(s)*

35 USC § 103 - OBVIOUSNESS REJECTION

The following is a quotation of 35 U.S.C. § 103(a) that forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

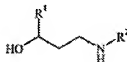
Graham v. John Deere Co. set forth the factual inquiries necessary to determine obviousness under 35 U.S.C. §103(a). See *Graham v. John Deere Co.*, 383 U.S. 1, 148

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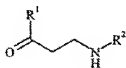
USPQ 459 (1966). Specifically, the analysis must employ the following factual inquiries:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8, 21-25, 31-33, 35 and 36 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Hill, et al.* Applicants claim The instant invention claims a



process for the preparation of a compound of formula and/or an addition salt of a proton acid, wherein R^1 represents C_{1-8} -alkyl or phenyl and R^2 represents alkyl, cycloalkyl, aryl or aralkyl, each aryl or aralkyl being optionally further substituted with alkyl, alkoxy and/or halogen which process comprises the following steps: a) reacting a mixture comprising: (i) a methyl ketone of formula: CH_3COR^1 wherein R^1 is as defined above, and (ii) a compound of formula: H_2N-R^2 and/or an addition salt of proton acid, wherein R^2 is as defined above, and (iii) formaldehyde or a source of formaldehyde selected from the group consisting of formaldehyde in aqueous solution, 1,3,5-trioxane, paraformaldehyde and mixtures thereof, in the presence of a solvent selected from the group consisting of water, aliphatic alcohols, cycloaliphatic alcohols and mixtures thereof and optionally a proton acid to provide a β -keto amine of



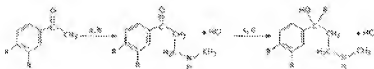
the formula and/or an addition salt of a proton acid and b) reducing the carbonyl group of β -keto amine to afford a compound of formula I and/or an addition

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salt of a proton acid wherein the step a) is carried out at a pressure above 1.5 bar.

The Scope and Content of the Prior Art (MPEP §2141.01)

Hill, *et al.* teaches the following method



wherein a) $(\text{HCHO})_n$, MeNH_2

HCl , EtOH , HCl , reflux; b) H_2O , steam distillation, MeOH ; c) NaBH_4 , 2-propanol/ H_2O ;

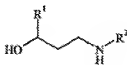
d) MeOH , HCl ; $\text{EtOH}/\text{Me}_2\text{CO}$; R is H or Cl.

The Difference Between the Prior Art and the Claims (MPEP §2141.02)

The difference between the prior art of Hill, *et al.* and the instant invention is that there is that step a) in the instant application is carried out at a pressure above 1.5 whereas in the prior art reference the first step is carried out under reflux and then steam distillation.

Prima Facie Obviousness-The Rational and Motivation (MPEP §2142-2413)

In *In re Aller*, 220 F.2d 454, 105 USPQ 233 (CCPA 1955), it was well established that merely modifying the process conditions such as temperature and concentration is not a patentable modification absent a showing of criticality. For example, it is obvious



to modify the preparation of a compound of

comprising step a)

and step b) as disclosed in claim 1 to improve the product yield since a similar reaction

using different conditions in step 1 was already taught by the prior art. Specifically, changing the reaction conditions of step 1 as seen in the claim 1 absent unexpected results is deemed obvious over the *Hill, et al.* reference. Therefore, it would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to attempt to improve the known process by modifying the reaction conditions (i.e. carrying out the first step under pressure) to increase the product yield. A strong prima facie obviousness has been established.

III. Objection

Dependent Claim Objections

Dependent Claim 34 is also objected to as being dependent upon a rejected based claim. To overcome this objection, Applicant should rewrite said claims in an independent form and include the limitations of the base claim and any intervening claim.

IV. Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 5:30 AM-2:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shawquia Young/

/Kamal A Saeed, Ph.D./

Primary Examiner, Art Unit 1626